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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,204	09/10/1999	DAVID M. STERN	52209-A-PCT-	3891

7590 12/26/2002

JOHN P WHITE
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NEW YORK, NY 10036

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/394,204

Applicant(s)

Stern et al

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22 and 26 is/are pending in the application.
- 4a) Of the above, claim(s) 22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 20-22 and 26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
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| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) Paper No(s). |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). | 6) Other: |

Art Unit: 1647

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/15/02 has been entered.
2. Newly submitted claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 26 is the invention of Group VI and not elected Group V, for the reasons made of record in Paper No: 7. Moreover, the products of claim 26 are distinct from a method for evaluating unknown agents ability to inhibit binding of ERAB to amyloid-beta peptide because (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). Note further that claim 20 is directed to a method and not a product, as incorrectly recited in non-elected claim 26.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 22 & 26 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1647

3. The rejection of claims 20-21 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn due to the amendment of the claims.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Applicants' arguments filed 10/15/02 has been considered but are not found persuasive.
6. Claims 20-21 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a binding assay using the specific purified ERAB polypeptide of SEQ ID NO 2 and the amyloid-beta polypeptide structurally described on pages 1-2 of the specification, does not reasonably provide enablement for any method in which the required components necessary to practice the method are structurally and functional uncharacterized (i.e., as it relates to generic uncharacterized ERAB polypeptides). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 11, and as follows.

In contrast to Applicants' assertions on page 6 of the response, canceling nonelected claims does not address the rejection made of record. The issue remains that no structure for the "ERAB polypeptide" required to practice the current method of claim 20 is known or recited, in

Art Unit: 1647

which the metes and bounds encompassed by the name "ERAB polypeptide" is unknown based on the open-ended definition of such on pages 14-17 of the specification. Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for any ERAB protein's function that is a required component for knowing how to successfully make and use the instant method would prevent the skilled artisan from determining whether any modification or mutation to the specific human ERAB protein of SEQ ID NO: 2 could be made which retains the desired function of the instant invention, because any random mutation or modification manifested within such a ERAB protein would be predicted to adversely alter its biologically active 3-dimensional conformation, and therefore, a method that the skilled artisan would not know how to make and/or use, without undue experimentation to determine otherwise; consistent with the teachings of Rudinger previously made of record.

Accordingly, *Ex parte Maizel* (27 USPQ2d 1662 at 1665) held (i.e., as it relates to the components required to practice the claimed invention):

Appellants have not chosen to claim the DNA [product] by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt*, 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA [product] segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

Art Unit: 1647

7. Claim 21 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for using improper Markush language, for the reasons made of record in Paper No: 11.

Again, elements within a Markush group are required to possess some structural similarity *among themselves* (e.g., be classified within the same class), versus some alleged affinity "at the ERAB polypeptide active site", which clearly remains not the situation here. See M.P.E.P. 2173.05(h). Thus, Applicants' arguments are not persuasive.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RC
Robert C. Hayes, Ph.D.
December 18, 2002

Gary d Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800